REMARKS

Claims 3, 11, 12, 13, 14, 17, 18, 19, 20, 22, 28, 29, 30, 31, 32, 33, 34, 35, 36, 44, 47, 48, and 49 have been cancelled. Claims 40-43 have been amended. New claims 50-57 have been added. Claims 1, 2, 4-10, 15-16, 21, 23-27, 37-43, and 50-57 are now pending in the application. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

7. The Examiner rejects claims 3 and 22 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claims 3 and 22 have been cancelled. The Examiner states that the dependent claims cited in this rejection fail to further limit the claims from which they depend. The Examiner suggests that the claims be placed in a product –by-process format. The Examiner also suggests that the claims should be drafted in terms of methods of making a plant by comprising transforming the exemplified plant of claim 2 or 21. New claims 54-57 reflect that suggestion.

8. The Examiner rejects claims 18-20 and 47-49 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner states that the term "single gene conversion" is used contrary to its accepted meaning. Claims 18-20 and 47-49 have been cancelled and new claims 50-57 have been added. The term "single gene conversion" is no longer used in the claims. It has been replaced with the term "backcross conversion".

REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH

9. The Examiner rejects claims 3, 9-20, 22, 28-44 and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. The Applicant traverses the rejection. Claims 3, 11, 12, 13, 14, 17, 18, 19, 20, 22, 28, 29, 30, 31, 32, 33, 34, 35, 36, 44, 47, 48, and 49 have been cancelled in order to expedite prosecution. Claims 40, 41, 42, and 43 have been amended. New claims 50-57 have been added.

The Examiner rejects claims 9-11 which are to the F1 hybrid plant. The Applicant points out that on page 38 of the application, Table 3 contains mean values of F1 plants made with PH0GC as one parent and numerous other maize inbreds as the second parent. The Examiner also states that the U.S. Court of Appeals Federal Circuit's decision states that "a showing of 'possession' is ancillary to the *statutory* mandate that the specification will contain a written description of the invention and that a showing of possession alone does not cure the lack of written description of the specification, as required by statute." Applicant points out that not only possession is shown via Table 3 but the requirement of written description is fulfilled by the fact that a seed deposit is made and F1 plants made with PH0GC as a parent will contain all of the homozygous alleles of PH0GC. Further, one of ordinary skill in the art would know how to cross PH0GC with another maize plant. The F1 hybrid seed and plant produced using PH0GC, regardless of the other maize plant used, is identifiable because it will have one set of alleles coming from PH0GC. One of ordinary skill in the art would be able to run a molecular profile on PH0GC and the F1 hybrid and be able to identify the F1 hybrid as being produced from PH0GC. Seed pericarp tissue, which is solely maternal in origin, can be used to discern the maternal or paternal origin of the allele sets if necessary. See page 16 of Poethig, R.S. 1982. Maize, the plant and its parts. In: W.F. Sheridan (Ed.) Maize for Biological Research, University of North Dakota Press, Grand Forks, ND. pp. 9-18, submitted as Appendix A.

The Examiner rejects claims to transformed plants of PH0GC and backcross conversion plants of PH0GC. The claims to transgenic plants and backcross conversions are in new claims 50-57. The Examiner states that, "the claims encompass any transgenic plant using Applicant's PH0GC maize plant comprising, for example, transgenes encoding transcription factors, which are

known to be capable of affecting the expressing of multiple genes and expression of multiple traits within a transformed plant." The claims include the well known methods of producing backcross and transgenic conversion plants. The product by process claims are further limited by specified conversion or transgenic traits, which include the traits of insect resistance, herbicide resistance, disease resistance, waxy starch, decreased phytate, and male sterility. The Applicant is claiming PH0GC or a limited set of plants derived therefrom that have obtained significant genetic contribution from PH0GC.

Applicant respectfully points out that examples of transgenes, genes, and traits that can be backcrossed into the PH0GC are given in the application on page 21, lines 16-34, and also on page 23, line 20, through page 33, line 4. In order to expedite prosecution new claims 51 and 55 list the type of traits that may be conferred by backcross conversions and transgenes. Claim 51 also specifies that PH0GC is used at least twice as a recurrent parent in the development of a backcross conversion plant. Breeders, by using molecular markers, may obtain up to 98% genome identity between the backcross conversion and the recurrent parent after two backcrosses. See Marker-assisted Selection in Backcross Breeding, Openshaw, S.J. et al. Marker-assisted selection in backcross breeding. In: Proceedings Symposium of the Analysis of Molecular Data, August 1994, pp. 41-43. Crop Science Society of America, Corvallis, OR (1994) included as Appendix B. Inbred PH0GC transformed to comprise a transgene is also easily identifiable through the use of molecular markers. The transgenic version of PH0GC would have the same molecular profile as PH0GC, with the possible exception of a marker used in the profile that is located at the site of transgene insertion. However, in this case, the plethora of other identical markers would identify the line as a transgenic variant of PH0GC. This remains true regardless of the trait conferred by the transgene.

In the specification on page 4, lines 7-13, it states, "Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that

carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." The method of backcrossing genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art. The method has been successfully used since the 1950's (see pages 585-586 of Wych, 1988 included in the Information Disclosure Statement). In the specification, on page 21, lines 16-34, there is a description of how to backcross traits into PH0GC, which includes the claimed traits. Examples of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross." Wych (1988) on page 585-86, also submitted in the information disclosure statement, discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. In fact, many commercial products are produced in this manner, and those of ordinary skill in the art consider the F1 hybrid produced with the male sterile (backcross conversion) inbred to be the same variety as the F1 hybrid produced with the non-backcross conversion inbred.

As a result of the repeated use of the recurrent parent, the backcross conversion has many genetic alleles in common with the recurrent parent. Thus, genetic analysis may be used as a means of identifying the backcross conversion. The F1 hybrid made with a transgenic version or a backcross conversion of PH0GC is also identifiable by the use of genetic markers, because the hybrid would contain one set of alleles from each parent. The Applicant

further points out that in a backcross conversion both parental lines are well characterized because the deposited line is repeatedly used as a parent.

The Examiner rejects claims 37-39. Claims 37-39 are directed to growing out an F1 hybrid in which PH0GC is a parent and searching for PH0GC inbred seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH0GC seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

The Examiner rejects claims 15, 16, 40, and 42. These claims are to methods of breeding with PH0GC. Applicant points out that anyone of skill in the art would know how to utilize the well established breeding methods with PH0GC. Description of such occurs throughout the specification and descriptions can also be found in introductory plant breeding books. One of ordinary skill in the art would know how to cross PH0GC with another plant. One of ordinary skill in the art would know how to self the plant produced through the cross for successive filial generations. The Applicant requests that the Examiner specifically state the basis for the rejection to the method claims.

The Examiner rejects claims 40, 41, 42, and 43. Claims 40-43 remain pending and have been amended. Claim 40 is to the method of producing a first generation PH0GC-derived hybrid maize plant. Claim 41 is to the first generation F1 PH0GC-derived maize plant produced by the method of claim 40. The first generation F1 plant is identifiable through both breeding records and molecular marker techniques. Claim 42 is to the method of selfing the first generation hybrid PH0GC for successive filial generations. This is a basic and well known breeding methodology, and the use of this methodology with PH0GC is described in the specification on page 21, lines 1 to 15.

Claim 43 is to plants derived from claim 42 that have at least 50% of their genetics derived from PH0GC. These claimed plants are clearly described by

their method of production, which requires the use of PH0GC. Such plants must be produced through the use of PH0GC and the Examiner acknowledges that PH0GC is clearly identified. Further, Applicant has added the limitation of at least 50% inheritance from the PH0GC side of its pedigree to further emphasize the significant influence of PH0GC in the claimed product. Genetic inheritance has been accepted by both courts and governmental agencies as an accurate and reliable means of identification. In paternity cases courts routinely compel genetic testing of putative fathers to establish paternity, and federal law mandates that states have laws requiring that genetic test results be admissible in such cases without the necessity for foundation testimony or other proof. 42 U.S.C. 666(a)(5)(F)(iii)(Supp. V 1999). In such cases, a child will, on average, inherit 50% genetic contribution from each parent. Similarly, the plants produced by the method of claim 42 will also, on average, inherit 50% genetic contribution from each parent.

The Examiner states that, "the disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described". Applicant requests that the Examiner examine the sufficiency of description of claim 43 with all of its claim limitations, including the limitation that the progeny be produced by the method of claim 42, with the use of PH0GC and retaining at least 50% genetic contribution from PH0GC. One of ordinary skill in the art would know how to cross PH0GC to develop an F1 hybrid and also how to self plants derived from the cross with PH0GC. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C. 112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed."

10. The Examiner rejects claims 30-32 and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Applicant traverses the rejection but has cancelled claims 30-32 and 47-49 in order to expedite prosecution.

11. The Examiner rejects claims 3, 9-20, 28-44, and 47-49 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant traverses the rejection. Claims 3, 11-14, 17-20, 28-36, 44, and 47-49 have been cancelled in order to expedite prosecution.

The Examiner states that arguments of the Applicant have not been found persuasive "because Applicant does not teach which markers to use in the identification method that would be useful for reliably identifying a maize plant as a progeny of PH0GC, and not for instance, maize plant PH36E." The Applicant has fulfilled this written description requirement through the seed deposit of PH0GC. As described in the specification, lines 8-23 on page 16, the seed deposit allows one of ordinary skill to run a molecular profile of PH0GC. One of ordinary skill in the art would know how to obtain markers useful for such a profile. For example, the Applicant refers the Examiner to the Maize DB on the world wide web at agron.missouri.edu for an extensive listing of Markers that could be reliably used for this purpose. To expedite prosecution, Applicant submits the molecular profile of inbred line PH0GC in the declaration of Dinakar Bhattramakki attached hereto as Appendix C. Further, Applicant amends the specification to include such SSR profile. Such SSR profile is not new matter, as it is an inherent feature of inbred line PH0GC, a representative sample of which has been deposited with the ATCC. For example, see Ex parte Marsili, Rosetti, and Pasqualucci, 214 USPQ 904 (1972), in which the Patent and Trademark Office Board of Appeals held that it was not new matter to amend the structure of a compound when a more refined analytic investigation showed a corrected formula. The Board, relying on well established cases of In re Nathan et al, 51 CCPA 1059, 328 F.2d 1005, 140 USPQ 601 (1964); In re Sulkowski, 487 F.2d 920, 180 USPQ 46 (CCPA 1973); Spero v. Ringold, 54 CCPA 1407, 377 F.2d. 652, 153 USPQ 726 (1967), and Petisi et al. v. Rennhard et al., 53 CCPA 1452,

363 F. 2d 903, 150 USPQ 669 (1966) concluded that the "products described, exemplified and claimed by Appellants inherently had and have now the structure given in the amendment in question. Consequently, the changes made in this amendment do not constitute new matter. Marsili at 906. Similarly, in the present case, inbred line PH0GC inherently had and still has the SSR marker profile being added. One of ordinary skill in the art can use molecular markers to identify PH0GC, a transgenic version of PH0GC, a backcross conversion of PH0GC and the F1 plant of the transgenic version and backcross conversion of PH0GC.

The Examiner goes on to state that "claims 9-11, 13, 14, 17-20, 28-30, 32, 33, 36-39, 41, 43, and 47-49 are rejected as not enabled for the lack of written description because Applicant has not adequately taught one of skill in the art how to make and use the claimed invention." The Examiner goes on to cite Hunsperger et al., Kraft et al. and Eshed et al. and states that they teach "it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. The Examiner states that, "Hunsperger *et al* teach that the introgession of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46)." Applicant's respectfully disagree that this is what is taught by Hunsperger et al. Hunsperger et al. teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger et al. merely discusses the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger et al. succeeded in incorporating the gene into petunia plants of different genetic backgrounds. Therefore, Hunsperger et al. support the fact that one can introgress a specific trait into a recurrent parent through backcross conversion. Applicant's specification provides ample disclosure of starting materials such as maize inbred PH0GC, a discussion of

traditional breeding methods, and examples of transgenes and naturally occurring genes that may be used in such methods. Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, state that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." The teaching of Hallauer relates specifically to corn breeding and corn inbred line development.

The Examiner goes on to state that, "Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323)." Applicant disagrees that the article states such points. Kraft et al. make no mention of a plant comprising a single gene conversion or the use of backcrossing. Further, Kraft et al. relates to linkage disequilibrium and fingerprinting in sugar beet, a crop other than maize. Kraft et al. state, on p. 326, first column, "The generality of our results for other crop species needs to be investigated."

It is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on it's web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix D.

An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross."

The Examiner goes on to state that, "Eshed *et al* teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may effect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815). The Applicant would like to point out on page 1816, column 1, lines 1-5 of the Eshed et al. article it states, "Recent studies that detected epistasis of selected QTL in Drosophila (Long et al. 1995), soybean (Lark et al.1995) and maize (Doebley et al.1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Claim 51 has been amended to expedite prosecution. In claim 51, the genes transferred into PH0GC are now limited to the traits of herbicide resistance, insect resistance, disease resistance, male sterility, decreased phytate, and waxy starch.

The Examiner goes on to state that, "At claims 18-20, 37-39, and 47-49, the claimed method for producing inbred PH0GC and PH0GC maize plants or parts thereof comprising one or more 'single gene conversion' are not enabled in view of Applicant's specification because Applicant states that neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in detail and that it is not known how the genotype would react with the environment."

Applicant respectfully points out that claims 37-39 are to a method that is referred to as "chasing selfs" in the corn research industry. Please note that claim 37 reads, "A process for producing inbred PH0GC, representative seed of which have been deposited under ATCC Accession No. PTA-4530, comprising: (a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred PH0GC *said collection also comprising seed of said inbred* ...." Emphasis added. As stated earlier claims 37-39 are directed to growing out an F1 hybrid in which PH0GC is a parent and searching for PH0GC inbred seed that was mistakenly bagged with the hybrid seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. This claim covers the method of searching for inbred PH0GC seed within a bag of hybrid seed. The method is clearly described in the specification on page 5, line 21 through line 7 on page 6. One of ordinary skill in the art can practice such a method without undue experimentation. The Applicant requests that the Examiner withdraw his rejection to claims 37-39.

Claims 18-20 and 47-49 have been cancelled and replaced with new claims 50-57. Claims 54 and 55 are to the method of transforming PH0GC and the transformed plant with listed transgenes. These claims are similar to the claims suggested by the Examiner. New claims 50-53 are to the backcross conversions of PH0GC. The Examiner states that it would be undue trial and error experimentation by one of skill in the art to produce a "single gene conversion" or as now stated a "backcross conversion" of PH0GC. Applicant disagrees with the Examiner. As previously stated in this response, the specification, IDS references, and the seed organization of UPOV, all state that backcrossing a trait into an inbred maize plant is routinely practiced.

Claim Rejections under 35 U.S.C. § 102 and 103

The Examiner states that, "Claims 14, 41, and 43 remain rejected under 35 U.S.C. 102(b) as anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Rietmann (U.S. Patent No. 6,310,274)." Applicant traverses the rejection.

Applicant has cancelled claim 14. Applicant has amended claim 41 and claim 43. Claim 41 is limited to the F1 hybrid produced from one cross with PH0GC. Claim 43 is limited to progeny produced by the method of claim 42, which requires the use of PH0GC, and is further limited to progeny derlving at least 50% genetic contribution from PH0GC.

As evidenced by the declaration of Stephen Smith submitted as Appendix E, both PH0GC and its progeny within the scope of claim 43 are distinct from PH36E taught in U.S. Patent No. 6,310,274.

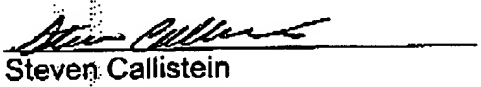
In light of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection to claims 41 and 43 under 35 U.S.C. 102 (b) and 103(a).

Claims 1, 2, 4-10, 15-16, 21, 23-27, 37-43, and 50-57 are now pending in the application. The amendments made herein do not in any way change the claim scope which the Applicant believes is allowable but is meant to hasten the issuance of the patent.

CONCLUSION

Applicant submits that in light of the foregoing amendments and the remarks, the claims 1, 2, 4-10, 15-16, 21, 23-27, 37-43, and 50-57 are in condition for allowance. Reconsideration and early notice of allowability is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,
Maryse Lafousse



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